

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Application No. : 10/803,126  
Inventor(s) : James Robert Schwartz et al.  
Filed : 03/17/2004  
Art Unit : 1616  
Examiner : Ernst V. Arnold  
Docket No. : 9183M&  
Confirmation No. : 4865  
Customer No. : 27752  
Title : AUGMENTATION OF PYRITHIONE ACTIVITY OR A  
POLYVALENT METAL SALT OF PYRITHIONE ACTIVITY BY  
ZINC-CONTAINING LAYERED MATERIAL

**DECLARATION OF JAMES R. SCHWARTZ UNDER 37 CFR 1.132**

Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22312-1450

Dear Sirs:

I, James Robert Schwartz, hereby declare and say the following:

1. I have been a full-time employee of The Procter & Gamble Company for 23 years and my current position with the company is Research Fellow, P&G Beauty. I hold a B.A. in Chemistry from Kenyon College, 1982 and a PhD in Chemistry from the University of Illinois, 1986.
2. I am one of the named inventors on the above-entitled application and am familiar with the August 17, 2010 Office Action in this application.
3. The claimed invention in the above-entitled application:

A composition comprising:

- a) from about 0.01 weight% to about 5 weight%, based on the total weight of the composition, of pyrithione or a polyvalent metal salt of a pyrithione, wherein the pyrithione or polyvalent metal salt of pyrithione is zinc pyrithione;

b) from about 0.001 weight% to about 10 weight%, based on the total weight of the composition, of a zinc-containing layered material which provides an augmentation factor greater than 1 wherein the zinc-containing layered material comprises an impurity containing hydroxy-containing basic zinc carbonate and further wherein the ratio of zinc-containing layered material to said pyrrithione or a polyvalent metal salt of pyrrithione is from about 1:2 to about 3:1.

4. To establish the impact that changes in zinc lability of basic zinc carbonate materials has on efficacy, the IMAC data from Study AD-50 was correlated to measured zinc lability reported in the present invention.

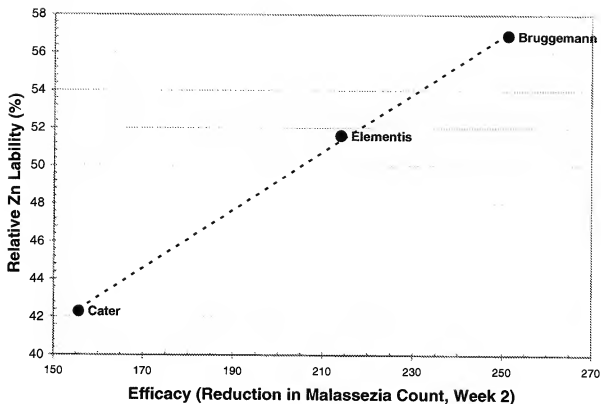
Data from the In Vivo Malassezia Automated Counting (IMAC) method measures the ability of an anti-dandruff product to reduce the population of Malassezia yeast on the scalp. There is a very strong relationship between reduction in Malassezia levels and resultant clinical efficacy (reduction in flake symptoms). Thus IMAC Malassezia reduction is a proxy measurement for anti-dandruff efficacy.

5. In IMAC Study AD-50, shampoo prototypes that differed only in the source of the basic zinc carbonate were evaluated for in vivo Malassezia reduction capability. This data is tabulated below in comparison to the zinc lability data for basic zinc carbonate materials of different origin reported in the present invention.

Table 1.

Source of Material	Relative Zinc Lability (%)	IMAC Efficacy (Reduction in Malassezia Count)
Bruggemann	56.9	251.2
Cater	42.3	155.7
Elementis	51.6	214.1

**GRAPH 1**

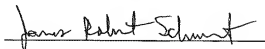


6. The data indicates a strong correlation between zinc lability and product efficacy, as expected from the mechanistic understanding: zinc lability is a measure of the ability of a material to release zinc ions, which are the source of the augmentation benefit.

Such differences of basic zinc carbonate without impurities (monophasic such as Cater and Elementis) vs. impurity containing basic zinc carbonate (e.g. Bruggemann) are important to the behavior of basic zinc carbonate, as the higher purity materials (closer to monophasic) have lower IMAC Efficacy (Reduction in Malassezia Count), as demonstrated in Table 1 and Graph 1.

7. In summary, this data demonstrates that Bruggemann-type basic zinc carbonate materials, which are impurity containing, are an important attribute of the claimed invention to achieve high performance.

8. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that the statements are made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001, Title 18, of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified application of any patent issued thereon.



James Robert Schwartz

Dated: Feb. 17, 2011

18 U.S.C §1001 Statements or Entries Generally

Whoever, in any matter within the jurisdiction of any department or agency of the United States knowingly and willfully falsifies, conceals, or covers up by any trick, scheme, or device a material fact, or makes any false, fictitious or fraudulent statements or representations, or makes or uses any false writing or document knowing the same to contain any false, fictitious, or fraudulent statement or entry shall be fined no more than \$10,000 or imprisoned not more than five years, or both.